DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Leonard Lee
31855 Date Palm Dr., Suite 153
Cathedral City, California 92234

SEP 1 2005

Dear Mr. Lee:

This is to inform you that the notification, dated June 15, 2005, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on June 23, 2005. Your notification concerns the substance called "Toona sinensis (A Juss.) M Roem" that you intend to market as a new dietary ingredient.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification for a new dietary ingredient. Your notification concerning "Toona sinensis" does not comply with the requirements of 21 CFR 190.6 and is incomplete. The following items were not included with your submission: (1) An original and two copies of the notification, (2) a description of the dietary supplement or dietary supplements that contains your new dietary ingredient, (3) the level of the dietary ingredient in the dietary supplement and (4) the conditions of use recommended or suggested in the labeling of the dietary supplement. Your notification describes the physical characteristics and edible uses for the tree, fruit, and leaves, but no information for the product that you intend to market.

Your notification provided three reference articles; the remainder consisted of citations and abstracts of the references that you relied on as evidence of safety. Any references to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. In addition, your notification did not include documented history of use of your new dietary ingredient as an article present in the food supply

Your notification provides some history of use for "Toona sinensis" as a traditional Chinese medicine but does not provide documented evidence of "Toona sinensis" used as an ingredient in a dietary supplement. Thus, FDA cannot make an evaluation of the safety of "Toona sinensis" based on the history of use information provided in your notification.

FDA is unable to determine whether the scientific studies cited in your notice provide an adequate basis for a conclusion that the dietary supplement will reasonably be expected to be safe because the information contained in your notice is incomplete. If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (http://www.cfsan.fda.gov/~lrd/cfr190-6.html), or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Moreover, from the information submitted in your notification, it appears that "Toona sinensis" is intended to treat a medical condition. Please be aware that under 21 U.S.C. 321(g)(1)(B), if a product is implicitly or expressly represented as being intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease, it may be subject to regulation under the drug provisions of the Act.

Your notification will be kept confidential for 90 days after the filing date of June 23, 2005. After the 90-day date, the notification will be placed on public display at FDA's Division of Dockets Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

Linda S. Pellicore

for Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition